UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**Note to Reader**
**January 15, 1998**

**Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.**

**The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.**

**There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.**

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

**Note:** This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket ( RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

**MEMORANDUM**

SUBJECT: Dietary Exposure Analysis for Methidathion in Support of the Reregistration Eligibility Decision.

FROM: Brian Steinwand
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: Mike Metzger, Chief
Risk Characterization Analysis Branch
Health Effects Division (7509C)

**Action Requested**

Provide a dietary exposure analysis to estimate the chronic, carcinogenic, and acute dietary exposure and risk from methidathion for uses which are being supported through reregistration.

**Discussion**

*Toxicological Endpoint:*

The Reference Dose (RfD) used in the analysis is 0.0015 mg/kg bwt/day, based on a NOEL of 0.15 mg/kg bwt/day from a long term toxicity study in dogs with an uncertainty factor of 100 that demonstrated elevated hepatic enzymes, gross hepatic lesions, chronic hepatitis, and red blood cell cholinesterase inhibition as endpoints (See RfD Peer Review Report, 11/10/93).

Methidathion is classified as a Group C - possible human carcinogen by the HED Carcinogenicity Peer Review Committee with evidence of carcinogenicity in mice (liver) and negative in the rat. Additional evidence from short-term tests or structure activity relationships were not supportive of a higher

classification. Thus, the evidence as a whole was not considered strong enough to warrant a quantitative estimation of human risk.

The endpoint for acute dietary risk assessment is the NOEL of 0.2 mg/kg bwt/day based on decreases in plasma, RBC, and brain ChE seen at the two week measurement.

*Residue Information*

Tolerances for methidathion are published in 40 CFR §180.298 (a), (b), and (c). Tolerances for methidathion residues are currently expressed in terms of methidathion *per se* in plant commodities [§180.298(a and c)] and in terms of the combined residues of methidathion, its oxygen analog, and its sulfoxide metabolites in animals [§180.298(b)]. The available data support the established tolerances in/on pome fruits, artichokes, cottonseed, mandarins, mangoes, olives, peaches, pecans, safflower seed, sorghum, stone fruit, sunflower seed, carambola, kiwifruit, longan, sugar apple, and walnuts; the established tolerances for residues in/on citrus fruits should be increased from 2 ppm to 4 ppm; tolerances on potatoes should be revoked as there are no registered uses on this crop (See RED chapter). Some anticipated residues and percent crop treated assumptions were used in the dietary risk analyses.

Acute Anticipated Residues were estimated using tolerance level residues and survey data from the USDA Pesticide Data Program (PDP) and were supplied by CBRS (See memo, W. Smith, 12/3/96) for the following commodities: orange pulp 0.33 ppm; orange juice 0.26 ppm; orange peel 0.114 ppm; grapefruit pulp 0.33 ppm; grapefruit juice 0.26 ppm; grapefruit peel 0.114 ppm; lemon pulp 0.33 ppm; lemon juice 0.001 ppm; lemon peel 0.114 ppm; lime pulp 0.33 ppm; lime juice 0.001 ppm; lime peel 0.114 ppm; apple juice 0.015 ppm; cottonseed oil 0.05 ppm; safflower oil 0.01 ppm; and sunflower oil 0.01 ppm.

*Results*

*Chronic Exposure:*

A summary of the residue information included in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population

and 22 subgroups. Percent crop treated data and anticipated residue data were used to calculate the Anticipated Residue Concentration (ARC) for those same population subgroups for certain commodities. Summaries of the TMRCs, ARCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3. A summary of the residue information and the associated ARCs using the recommended tolerance increases and or decreases and RAC revocations are attached as Table 5, and 6.

Existing tolerances (and a pending tolerance on corn) result in a TMRC which represents 43.8% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (<1 year old) occupies 160% of the RfD and Children (1-6 years old) occupies 111% of the RfD. (Note: deleting the pending use on corn does not result in acceptable risk levels in these two subgroups). The commodity which contributes most to this risk figure is milk at 130% (See Table 4). Incorporating the recommendations of CBRS (increasing the citrus tolerance from 2-4 ppm, deletion of potatoes, meat, milk, eggs, and poultry and without the pending use on corn) would result in a TMRC of 9.1% of the RfD for the U.S. general population, 11.9% for Non-Nursing Infants (<1 year old), and 22.5% for Children (1-6 years old) (See Table 6).

The analysis for methidathion is not a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with methidathion. Some refinements such as percent crop treated data and anticipated residues have been incorporated. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk from the uses recommended through reregistration, is not of concern. It should be noted however that the data refinements used are old (Percent crop treated 9/87 and Anticipated Residues 5/88) and should be updated.

Acute Exposure:

Two acute analyses were performed. Table 7 shows the results of the analysis using all presently registered commodities. Table 8 demonstrates results which would occur following the recommendations of CBRS.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern when results are compared to animal-derived data. The MOE values demonstrate that there is

cause for concern regarding the acute dietary exposure from methidathion both for existing and proposed uses:

Presently registered commodities result in the following MOEs: U.S. POP = 14.3; Infants (< 1 year) = 6.6; Children (1-6 years) = 6.6; Females (13+ years) = 20; and Males (13+ years) = 25.

Following the recommendations of CBRS results in the following MOEs: U.S. POP = 1.6; Infants (< 1 year) = 6.6; Children (1-6 years) = 6.6; Females (13+ years) = 25; and Males (13+ years) = 33.3.

All subgroups exceed the Agency's level of concern regarding acute exposure.

Attachments

cc: DRES; Caswell
378B

# TABLE 7

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 09:44 Tuesday, December 10, 1996 47

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *NAME: METHIDATHION | | STUDY | RDV | NOEL | SF | STUDY TYPE | SPECIES | EFF. LEV. | CORE GRADE | DOC. NO.* |
| *CASWELL NO: 378B | CFR NO: CFR180.298 | A | 00000.0010 | 000004.000 | 000100 | Chronic | Dog | Systemic | Blank | 0000000581* |
| *CAS NO: 00950-37-8 SHAUGHNESSY NO: 100301 B | | | | | | | | | | * |
| *STATUS CODES: | | C | | | | | | | | * |
| *RDV INFO: The LD value used in this analysis is 0.01 MG/KG of BODY WEIGHT/DAY | | | | | | | | | | * |
| *FILE INFO: No Tolerance Data Are Used--Without User Modifications. | | | | | | | | | AR DATA: | No User Modifications* |

-U.S. POP.--48 STATES

ESTIMATED % OF POTENTIAL — MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
|---|---|---|---|
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 99.77 | 0.001486 | 14.86 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 21 | 7 | 3 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

0INFANTS(<1 YEAR)

ESTIMATED % OF POTENTIAL — MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
|---|---|---|---|
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 92.26 | 0.003987 | 39.87 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 69 | 32 | 16 | 11 | 7 | 4 | 3 | 2 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |

0CHILDREN(1-6 YRS)

ESTIMATED % OF POTENTIAL — MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
|---|---|---|---|
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 99.95 | 0.003740 | 37.40 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 57 | 31 | 18 | 10 | 6 | 3 | 2 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |

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1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 09:44 Tuesday, December 10, 1996 48

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *NAME: METHIDATHION | STUDY | RDV | NOEL | SF | STUDY TYPE | SPECIES | EFF. LEV. | CORE GRADE | DOC. NO.* |
| *CASWELL NO: 378B CFR NO: CFR180.298 | A | 00000.0010 | 000004.000 | 000100 | Chronic | Dog | Systemic | Blank | 0000000581* |
| *CAS NO: 00950-37-8 SHAUGHNESSY NO: 100301 | B | | | | | | | | * |
| *STATUS CODES: | C | | | | | | | | * |

*RDV INFO: The LD value used in this analysis is 0.01 MG/KG of BODY WEIGHT/DAY *

*FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications*

-FEMALES(13+ YRS)

| | ESTIMATED % OF POTENTIAL | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY | |
|---|---|---|---|
| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 99.82 | 0.001065 | 10.65 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 14 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

OMALES(13+ YRS)

| | ESTIMATED % OF POTENTIAL | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY | |
|---|---|---|---|
| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 99.92 | 0.001056 | 10.56 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 12 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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General U.S. Population

Exposure = RDV x X
= 0.01 x 1.4
High End Exposure = 0.014

MOE = Noel ÷ Exposure
= 0.2 mg/kg/day ÷ 0.014 mg/kg/day
MOE = 14.3

Infants (< 1 year)

Exposure = RDV x X
= 0.01 x 3
High End Exposure = 0.03

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0.03 mg/kg/day
MOE = 6.6

Children (1-6 years)

Exposure = RDV x X
= 0.01 x 3
High End Exposure = 0.03

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0.03 mg/kg/day
MOE = 6.6

Females (13+ Years:

Exposure = RDV x X
= 0.01 x 1
High End Exposure = 0.01

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0.01 mg/kg/day
MOE = 20

Males (13+ Years:

Exposure = RDV x X
= 0.01 x .8
High End Exposure = 0.008

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0. 008 mg/kg/day
MOE = 25

# TABLE 8
## RED

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 09:05 Tuesday, December 10, 1996 27

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *NAME: METHIDATHION | STUDY | RDV | NOEL | SF | STUDY TYPE | SPECIES | EFF. LEV. | CORE GRADE | DOC. NO.* |
| *CASWELL NO: 3788 CFR NO: CFR180.298 | A | 00000.0010 | 000004.000 | 000100 | Chronic | Dog | Systemic | Blank | 0000000581* |
| *CAS NO: 00950-37-8 SHAUGHNESSY NO: 100301 | B | | | | | | | | * |
| *STATUS CODES: | C | | | | | | | | * |

*RDV INFO: The LD value used in this analysis is 0.01 MG/KG of BODY WEIGHT/DAY *

*FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications*

-U.S. POP.--48 STATES

| | ESTIMATED % OF POTENTIAL | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY | |
|---|---|---|---|
| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 98.46 | 0.000775 | 7.75 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 11 | 4 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

0INFANTS(<1 YEAR)

| | ESTIMATED % OF POTENTIAL | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY | |
|---|---|---|---|
| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 71.75 | 0.002252 | 22.52 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 24 | 18 | 13 | 9 | 5 | 3 | 2 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |

0CHILDREN(1-6 YRS)

| | ESTIMATED % OF POTENTIAL | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY | |
|---|---|---|---|
| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 99.20 | 0.002059 | 20.59 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 31 | 20 | 10 | 6 | 3 | 2 | 2 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |

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*NAME: METHIDATHION STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.*
*CASWELL NO: 3788 CFR NO: CFR180.298 A 00000.0010 000004.000 000100 Chronic Dog Systemic Blank 0000000581*
*CAS NO: 00950-37-8 SHAUGHNESSY NO: 100301 B *
*STATUS CODES: C *
*RDV INFO: The LD value used in this analysis is 0.01 MG/KG of BODY WEIGHT/DAY *
*FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications*

-FEMALES(13+ YRS)

| | ESTIMATED % OF POTENTIAL | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY | |
|---|---|---|---|
| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 98.43 | 0.000597 | 5.97 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 8 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

0MALES(13+ YRS)

| | ESTIMATED % OF POTENTIAL | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY | |
|---|---|---|---|
| ESTIMATES BASED ON | PERSON DAYS THAT ARE USER-DAYS | MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
| TOLERANCES: | 0.00 | 0.000000 | 0.00 |
| ANTICIPATED RESIDUES: | 99.10 | 0.000481 | 4.81 |

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

| | 0 | .2 | .4 | .6 | .8 | 1 | 1.2 | 1.4 | 1.6 | 1.8 | 2 | 3 | 4 | 5 | 10 | 15 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOLERANCES: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANTICIPATED RESIDUES: | 100 | 5 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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General U.S. Population

**Exposure = RDV x X**
**= 0.01 x 1.2**
**High End Exposure = 0.012**

**MOE = Noel ÷ Exposure**
**= 0.2 mg/kg/day ÷ 0.012 mg/kg/day**
**MOE =16.6**

Infants (< 1 year)

Exposure = RDV x X
= 0.01 x 3
High End Exposure = 0.03

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0.03 mg/kg/day
MOE = 6.6

Children (1-6 years)

Exposure = RDV x X
= 0.01 x 3
High End Exposure = 0.03

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0.03 mg/kg/day
MOE = 6.6

Females (13+ Years:

Exposure = RDV x X
= 0.01 x .8
High End Exposure = 0.008

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0.008 mg/kg/day
MOE = 25

Males (13+ Years:

Exposure = RDV x X
= 0.01 x .6
High End Exposure = 0.006

MOE = Noel + Exposure
= 0.2 mg/kg/day + 0.006 mg/kg/day
MOE = 33.3

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